FDA 510(k) Premarket Notification

K243444 BIOCERAM AZUL® HEAD

CLEARED

Dec 5, 2024
29 days to decision

K243444 · Product code: **LZO** · Orthopedic
Source: https://www.510kdatabase.net/k243444/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Nov 6, 2024
Decision date	Dec 5, 2024
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kyocera Corporation**
Location	Kyoto, JP
Contact	Yoshimi Amano
Website	http://global.kyocera.com/
510(k) history	1 submissions · 1 cleared · 2024-2024

Kyocera Corporation is a global engineering company with a manufacturing facility in Kyoto, Japan. The company develops advanced materials and technologies across multiple industries, including medical devices. Kyocera has received FDA 510(k) clearance from total submission. The company specializes in Orthopedic devices, representing 100% of its FDA 510(k) submissions. The latest clearance was granted in 2024, confirming active regulatory engagement. Explore Kyocera's cleared device names, product codes, and clearance dates in the 510(k) database to learn more about their...